REMARKS

Entry of the foregoing and reconsideration of the application identified in caption, as amended, pursuant to and consistent with 37 C.F.R. §1.116 and in light of the remarks which follow, are respectfully requested.

By the above amendments, claims 26 and 29 have been amended to depend from claims 25 and 28, respectively. Claim 35 has been amended to delete the phrase "having a homogeneous thickness." Claim 37 has been amended to delete the word "homogeneous." Entry of the above amendments is proper at least because they are effective to place the application either in condition for allowance or in better form for appeal. See M.P.E.P. §714.12.

In the Official Action, claims 14-43 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Withdrawal of this rejection is respectfully requested for at least the following reasons.

It is well established that "If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met." M.P.E.P. §2163. In the present case, the skilled artisan would have recognized that by disclosing that a major portion of the granules are coated with at least one biocompatible and biodegradable layer of a polymer (see original claim 1), Applicants were in possession of the embodiment in which a major portion of the surface area of the granules are coated with at least one layer of a polymer. Applicants' disclosure contains numerous references to the surface characteristics of the granules, and it is apparent from such disclosure that Applicants consider the surface area to be a fundamental characteristic of the granules. Accordingly, when taken as a whole, and taking into consideration the level of skill in the art, Applicants' disclosure provides

written descriptive support for the embodiment in which a major portion of the surface area of the granules is coated with at least one layer of a polymer.

Concerning claim 26, Applicants note that written descriptive support for such claim can be found in the instant specification at least at paragraph [0020] of the published application. Accordingly, for at least the above reasons, withdrawal of the §112, first paragraph, rejection is respectfully requested.

Claims 14-43 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Concerning claim 14, Applicants respectfully submit that the skilled artisan would have recognized that the term "a major portion of the surface area" refers to a majority of the surface area. In addition, the rejection of claims 26 and 29 is moot in view of the above amendments, in which such claims have been amended to depend from claims 25 and 28, respectively. In this regard, claims 25 and 28 provide antecedent basis for the terms "micropores" and "macropores", respectively. The rejection of claim 35 is moot in view of the above amendments, in which the term "homogenous thickness" has been deleted from such claim. Accordingly, for at least the above reasons, withdrawal of the above §112, second paragraph, rejection is respectfully requested.

Claims 14-20, 23, 32, 33 and 38-43 stand rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 4,645,503 (*Lin et al*) in view of U.S. Patent Application Publication No. US 2002/0016636 (*Ricci et al*). Claims 21, 22, 24, 25 and 28 stand rejected as being obvious over *Lin et al* in view of *Ricci et al*, and further in view of U.S. Patent No. 5,338,772 (*Bauer et al*). Claim 31 stands rejected as being obvious over *Lin et al* in view of *Ricci et al*, and further in view of U.S. Patent No. 4,610,692 (*Eitenmuller et al*). Withdrawal of these rejections is respectfully requested for at least the following reasons.

Lin et al does not disclose or suggest each feature recited in independent claim 14. For example, *Lin et al* does not disclose or suggest polymer-coated biocompatible and biodegradable granules fused together through polymer linkage, a major portion of the surface area of said granules being coated with at least one biocompatible and biodegradable layer of a polymer, said polymer layer having a thickness in a range of 2 μm to 300 μm corresponding to a weight fraction of about 4% to about 15% of the weight of said implant, as recited in claim 14.

By comparison, *Lin et al* discloses a cohesive mixture of hard filler particles and a binder composed of a thermoplastic polymer having fluid-flow properties at the selected temperature at or below about 60°C. See col. 2, lines 41-45. *Lin et al* merely discloses employing a mixture of hard filler particles and a binder, and has no disclosure or suggestion of granules that are coated with a polymer, a major portion of the surface area of said granules being coated with at least one biocompatible and biodegradable layer of a polymer.

Furthermore, *Lin et al* fails to disclose or suggest a polymer layer having a thickness in a range of 2 μm to 300 μm corresponding to a weight fraction of about 4% to about 15% of the weight of said implant, as recited in claim 14. Such deficiency has been acknowledged by the Patent Office at page 5 of the Official Action.

Ricci et al has bee relied on by the Patent Office for disclosing a polymer coating having a thickness of about 2 μm to about 50 μm and being in a range of 0.1% to 50% by weight. See Official Action at page 6. Respectfully, it would not have been obvious to modify *Lin et al* in view of *Ricci et al*'s disclosure of the use of such specific thickness and amount of a polymer coating. As noted by the Examiner, the polymer disclosed by *Ricci et al* is used for the purpose of controlling the resorption rate of the implant composition and as such, the specific thicknesses and amounts disclosed by *Ricci et al* are for obtaining such resorption rate characteristics. This function, however, is completely different from that of the polymer binder disclosed by *Lin et al*,

which has the purposes of providing sufficient particle cohesion and shape retention during the period of tissue ingrowth. See col. 2, lines 61-64. Clearly, in light of such stark functional differences, it would not have been obvious to employ the polymer thicknesses and amounts disclosed by *Ricci et al* in connection with the *Lin et al* binder.

The remaining secondary applied documents (i.e., *Bauer et al* and *Eitenmuller et al*) fail to cure the above-described deficiencies of *Lin et al*. In this regard, even if the remaining secondary applied documents would have been combined with *Lin et al* in the manner proposed by the Patent Office, the resulting combination nevertheless fails to disclose or suggest polymer-coated biocompatible and biodegradable granules fused together through polymer linkage, a major portion of the surface area of said granules being coated with at least one biocompatible and biodegradable layer of a polymer, said polymer layer having a thickness in a range of 2 μm to 300 μm corresponding to a weight fraction of about 4% to about 15% of the weight of said implant, as recited in claim 14.

For at least the above reasons, it is apparent that independent claim 14 is non-obvious over the applied art. Accordingly, withdrawal of the above §103(a) rejections is respectfully requested.

Claims 14-20, 23-25, 28, 30, 32-34 and 38-43 stand rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 6,869,445 (*Johnson*) in view of *Lin et al* and further in view of *Ricci et al*. Claims 21 and 22 stand rejected as being obvious over *Johnson* in view of *Lin et al*, and further in view of *Ricci et al* and further in view of *Bauer et al*. Claims 26 and 27 stand rejected as being obvious over *Johnson* in view of *Lin et al* and further in view of *Ricci et al* and further in view of U.S. Patent No. 6,455,024 (*Glajch et al*). Claim 29 stands rejected as being obvious over *Johnson* in view of *Lin et al* and further in view of *Ricci et al* and further in view of *Glajch et al*, and further in view of *Bauer et al*. Claim 31 stands rejected as being obvious

over *Johnson* in view of *Lin et al* and further in view of *Ricci et al* and further in view of *Eitenmuller et al*. Claims 35-37 stand rejected as being obvious over *Johnson* in view of *Lin et al* and further in view of *Ricci et al* and further in view of U.S. Patent No. 3,918,968 (*Kukla et al*). Withdrawal of these rejections is respectfully requested for at least the following reasons.

Johnson does not disclose or suggest each feature recited in independent claim 14. For example, *Johnson* does not disclose or suggest polymer-coated biocompatible and biodegradable granules fused together through polymer linkage, a major portion of the surface area of said granules being coated with at least one biocompatible and biodegradable layer of a polymer, said polymer layer having a thickness in a range of 2 μm to 300 μm corresponding to a weight fraction of about 4% to about 15% of the weight of said implant, as recited in claim 14. At page 11 of the Official Action, the Patent Office has acknowledged that *Johnson* fails to disclose or suggest a polymer layer having a thickness in a range of 2 μm to 300 μm corresponding to a weight fraction of about 4% to about 15% of the weight of said implant.

Furthermore, it would not have been obvious to modify *Johnson* to employ the thickness and weight percent ranges disclosed by *Ricci et al*. As noted above, the specific thickness and weight percent ranges disclosed by *Ricci et al* are for controlling the resorption rate of the implant composition. This function, however, is completely different from that of the polymer coating disclosed by *Johnson*, which is for permitting the beads to flow past each other readily, and protecting the beads from breakage and fragmentation during flow as in the filling and packing process. See col. 6, lines 29-33. Clearly, in light of such stark functional differences, it would not have been obvious to employ the polymer thicknesses and amounts disclosed by *Ricci et al* in connection with the *Johnson* coating.

The remaining secondary applied documents (i.e., *Lin et al*, *Bauer et al*, *Glajch et al*, *Eitenmuller et al* and *Kukla et al*) fail to cure the above-described deficiencies of *Johnson*. In

this regard, even if the remaining secondary applied documents would have been combined with *Johnson* in the manner proposed by the Patent Office, the resulting combination nevertheless fails to disclose or suggest polymer-coated biocompatible and biodegradable granules fused together through polymer linkage, a major portion of the surface area of said granules being coated with at least one biocompatible and biodegradable layer of a polymer, said polymer layer having a thickness in a range of 2 μm to 300 μm corresponding to a weight fraction of about 4% to about 15% of the weight of said implant.

For at least the above reasons, it is apparent that independent claim 14 is non-obvious over the applied documents. Accordingly, withdrawal of the above §103(a) rejections is respectfully requested.

Claim 14 stands provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being obvious over claims 36, 42 and 43 of copending Application No. 10/540,323. The Examiner is respectfully requested to hold this rejection in abeyance until the present application is deemed to otherwise be in condition for allowance.

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is earnestly solicited. If there are any questions concerning this paper or the application in general, the Examiner is invited to telephone the undersigned.

Respectfully submitted,

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